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VIA OVERNIGHT MAIL

November 5, 2001

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OFFICE OF SPECIAL NUTRITIONAL PRODUCTS LABELING AND DIETARY SUPPLEMENTS Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration HFS 811 200 C St. SW Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements of nutritional support:

Product:

DIGESTIVE FORMULA

Statements:

- Promotes healthy digestion
- Relieves the symptoms of overindulgence in food or drink
- Treats an upset stomach and occasional heartburn
- Prevents gas and bloating due to indigestion
- Helps reduce feelings of premature fullness
- Reduces occasional nausea due to overeating or indigestion
- Promotes the liver's ability to metabolize alcohol
- 100% natural symptom relief
- Digestive Formula is an all-natural approach to healthy digestion and the prevention of intestinal discomfort due to overindulgence in food and drink.
- Digestive Formula stops the symptoms of indigestion before they start by promoting healthy digestion.
- Key to the product's competitive advantage is its comprehensive approach to digestive function.
- Digestive Formula aids the healthy digestion of food, prevents and alleviates the symptoms of occasional indigestion: gas, bloating and

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much to eat and drink. heartburn, and helps the body recover when you've had a little too

- intolerance of foods, especially fatty foods. This special blend of digestive enzymes is helpful in relieving the
- artichoke extract to promote the production of digestive juices and to Digestive Formula delivers a highly-purified and standardized assist the liver's ability to metabolize alcohol.

Pharmanex, LLC, has substantiation that this statement is truthful and not misleading. I certify that the information contained in this notice is complete and accurate and that

Sincerely,

Carsten Smidt Senior Director of New Product

Research and Development